

STATE OF MICHIGAN
COURT OF APPEALS

BARBARA J MICHAL, as personal representative
of the estate of KRISTOPHER MICHAL,

UNPUBLISHED
September 18, 2003

Plaintiff-Appellant/Cross-Appellee,

v

PDK LABS, BDI PHARMACEUTICALS,
HAMMER CORPORATION, and 7 ELEVEN INC,

No. 234943
Saginaw Circuit Court
LC No. 00-032585-NP

Defendant-Appellees/Cross-
Appellants.

Before: Whitbeck, C.J., and White and Donofrio, JJ.

PER CURIAM.

Plaintiff Barbara J. Michal, as personal representative of the estate of decedent Kristopher Michal, appeals as of right an order granting the motions for summary disposition of defendants PDK Labs (PDK), BDI Pharmaceuticals (BDI), Hammer Corporation (Hammer), and 7 Eleven Inc (7 Eleven). Defendants cross-appeal, offering additional grounds for affirming the order. This case arose when Kristopher Michal died from an overdose of ephedrine, an ingredient in over-the-counter products manufactured and distributed by PDK, BDI, and Hammer, and sold at 7 Eleven convenience stores. Because we conclude that Michal failed to present evidence that would rebut the statutory presumption of manufacturer and seller nonliability, establish the existence of an alternative production practice that would have avoided the harm, or show that the harm was not caused by an inherent and necessary characteristic of the products in question, we affirm. We also affirm the dismissal of Michal's failure-to-warn claim, because it should have been obvious to a reasonably prudent consumer that serious harm can result from taking an overdose of an over-the-counter drug.

I. Basic Facts And Procedural History

At the time of his death, Kristopher Michal was a twenty-four-year-old man who was employed as a truck driver. On March 14, 1997, Kristopher Michal drove to Saginaw to pick up his former wife, Nicole Michal, from the airport. After meeting with Kristopher Michal's boss and eating at an area restaurant, the Michals drove to Grand Rapids. During that drive, Nicole Michal noticed several packages of a product called "Mini-Thins" or "Mini Two-Way Action" (Mini-Thins) on the floor of the truck, as well as a bottle of Maximum Strength Efedrin. Both these products contained ephedrine, a drug with stimulant properties that is used to treat asthma, among other conditions. Nicole Michal saw Kristopher Michal take "at least three or four

tablets” during the drive from Saginaw to Grand Rapids, although she did not specify which product he took. It is undisputed that this amount exceeded the recommended dose on the labels.

On arrival in Grand Rapids, as Kristopher Michal was unloading his truck, Nicole Michal saw him walk to the truck and lean on it, then fall to the ground, groaning and convulsing. The police and paramedics arrived in response to her 911 call and attempted to resuscitate Kristopher Michal; however, he died after being taken to the hospital. An autopsy determined that the cause of death was acute and chronic stimulant toxicity from ephedrine use. Both Nicole Michal and Barbara Michal (Michal), Kristopher Michal’s mother, were aware that Kristopher habitually used ephedrine products to help him stay awake and to give him more energy. Kristopher Michal had evidently experienced nausea and tremors as a result of using ephedrine products but, contrary to the label’s instructions, had never consulted a physician and did not stop using the products.

On March 13, 2000, Michal, as personal representative of Kristopher Michal’s estate, filed a five-count complaint against defendants. Count I alleged negligence and misconduct in connection with defendants’ manufacture, distribution, packaging, sale, and failure to warn of the dangers associated with use of Mini-Thins and Maximum Strength Efedrin. Count II alleged breach of implied warranty on various grounds, including inadequate labeling, failure to warn of the dangers of ephedrine, failure to adequately test the products, and that the products were not reasonably fit for the ordinary purpose for which they were used. Count III alleged breach of express warranty for manufacturing, marketing, distributing, and selling ephedrine-based products as a means to “increase energy, enhance the ability to stay awake and improve overall sense of well-being,” although the products were unsafe for these uses. Count IV alleged fraud and deceit for failing to reveal that ephedrine was addictive and dangerous, and for concealing studies about ephedrine’s dangers. Finally, Count V alleged negligent misrepresentation for representing that ephedrine products were a safe means to enhance energy and stay awake, and for concealing facts relating to ephedrine’s dangers and addictive properties.

Defendants filed separate motions for summary disposition, and also concurred in their codefendants’ motions. Hammer, manufacturer of Maximum Strength Efedrin, moved for summary disposition pursuant to MCR 2.116(C)(8) and (C)(10), stating that Kristopher Michal’s death was due to his unforeseeable misuse of ephedrine, for which a manufacturer or seller cannot be held liable. Hammer pointed out that Michal offered no evidence that it had represented its product as an energy enhancer. Hammer maintained that it was only required to warn of the risks associated with Maximum Strength Efedrin’s intended and reasonably foreseeable uses, and its warning label specified that it was for the temporary relief of asthma symptoms, that it should not be taken unless a doctor had diagnosed asthma, and that only one tablet should be taken every four hours. Further, Hammer noted that its product had been approved for sale by the Food and Drug Administration (FDA) and otherwise complied with federal standards, and therefore it could not be held liable under MCL 600.2946(5). Finally, Hammer argued that Michal could not bring a negligence claim based on product liability, which is a statutory claim that requires a plaintiff to offer evidence that the product was not reasonably safe when it left control of the manufacturer or seller, and also requires a plaintiff to provide information on a feasible alternative, neither of which Michal had done.

PDK and BDI moved for summary disposition under MCR 2.116(C)(10), arguing that Michal offered no admissible evidence that their product, Mini-Thins, caused Kristopher

Michal's death, and that the product in his pocket when he died was Hammer's, not theirs. Moreover, according to PDK and BDI, Mini-Thins had FDA approval and was in compliance with federal regulations, including labeling requirements, and Michal offered no evidence that PDK and BDI withheld information about their product. Finally, PDK and BDI argue that Kristopher Michal's misuse of their product was a complete defense.

7 Eleven moved for summary disposition pursuant to MCR 2.116(C)(8) and (C)(10), arguing that, as a seller, 7 Eleven could not be held liable for a product's harm unless its failure to exercise reasonable care proximately caused the harm, or unless 7 Eleven had breached an express or implied warranty regarding the product, which it had not.

Attached to Michal's brief in response to the motion for summary disposition were several articles about ephedrine misuse, as well as a pharmaceutical industry publication reporting that the FDA was considering making ephedrine products unavailable for over-the-counter sale. Also attached was a document purporting to be the text of a letter from the FDA to BDI instructing BDI to change the name "Mini-Thin" to avoid misrepresenting the product as a weight-loss drug, and directing BDI to increase the ratio of the expectorant guaifenesin to ephedrine to comply with requirements for over-the-counter bronchodilators. However, the letter was unsigned and undated, and did not appear to be an original document. Michal also provided a June 10, 1997 letter from the FDA warning Hammer that Maximum Strength Efedrin contained an inadequate amount of the drug guaifenesin, and was therefore misbranded because the directions for use on the label were inadequate for its intended purpose as a bronchodilator.

At the summary disposition hearing, Michal argued that MCL 600.2946(5) was inapplicable to defendants' products because they had not completed the FDA approval process, and furthermore that MCL 600.2946(5) was an unconstitutional delegation of legislative power to a federal agency. Michal maintained that Kristopher Michal's misuse of defendants' products did not bar her suit because the misuse was foreseeable. Michal asked the court to consider a summary of her experts' expected testimony regarding inadequate warnings and risks of use of products containing ephedrine, and also submitted several published articles discussing ephedrine misuse.

Defendants responded that even if MCL 600.2946(5) were unconstitutional, there were at least two other unchallenged statutory provisions that barred Michal's suit. Defendants observed that Michal offered no admissible evidence in support of her arguments, and even the inadmissible articles she proffered did not address defendants' particular products, nor did they state that ephedrine products were addictive. Defendants pointed out that Michal's argument relating to inadequate warnings on the label were unconvincing in light of the fact that Kristopher Michal ignored those instructions and warnings that were given.

The trial court found that Michal failed to provide any evidence that defendants' products had not been approved for safety and efficacy by the FDA and, moreover, had not supported the allegation that the products were mislabeled at the time the drug left the manufacturer's control. The trial court noted that Michal had limited her argument "to a list of experts that may testify at trial." Accordingly, the trial court ruled that Michal had failed to produce evidence showing a genuine issue of material fact respecting the applicability of MCL 600.2946(5). Without analysis, the trial court rejected the argument that MCL 600.2946(5) was an unconstitutional delegation of legislative powers to a federal agency.

Next, the trial court held that Michal failed to rebut the presumption that Hammer was not liable under MCL 600.2946, which applies to defendants that comply with state and federal safety standards. Moreover, the trial court noted that Michal never provided any evidence of a practical and more feasible alternative to defendants' products that would have prevented the harm without significantly impairing the products' desirability or creating equal or greater risks of harm, which is required to recover in a products liability action under MCL 600.2946(2).

Finally, the trial court held that Michal could not maintain any claims that were not based on the product-liability statute, and granted summary disposition with respect to the remainder of her claims on that basis; however, the trial court noted that even if Michal had been permitted to plead in the alternative, summary disposition of those claims would nonetheless have been justified on the ground that Michal failed to present any evidence to support them.

II. Summary Disposition

A. Standard Of Review

We review de novo the trial court's decision on a motion for summary disposition.¹

B. Legal Standards

To successfully oppose a motion under MCR 2.116(C)(10), the nonmoving party may not rely on mere allegations or denials, but must set forth evidence of specific facts showing that there is a genuine factual issue.² In evaluating the motion, the trial court must consider the affidavits, pleadings, depositions, admissions, and other evidence submitted by the parties, in the light most favorable to the party opposing the motion.³ The trial court may only consider "the substantively admissible evidence actually proffered in opposition to the motion," and may not deny the motion on "the mere possibility that the claim might be supported by evidence produced at trial."⁴ If the proffered evidence fails to establish a genuine issue of material fact, the moving party is entitled to judgment as a matter of law.⁵

Although a grant of summary disposition may be premature if granted before discovery on a disputed issue is complete,⁶ there must be a disputed issue before the court.⁷ To successfully oppose a motion for summary disposition on the ground that discovery is incomplete, a party "must at least assert that a dispute does indeed exist and support that

¹ *Maiden v Rozwood*, 461 Mich 109, 118; 597 NW2d 817 (1999).

² *Smith v Globe Life Ins Co*, 460 Mich 446, 455; 597 NW2d 28 (1999).

³ MCR 2.116(G)(5); *Quinto v Cross & Peters Co*, 451 Mich 358, 362; 547 NW2d 314 (1996).

⁴ *Maiden*, *supra* at 121.

⁵ MCR 2.116(C)(10), (G)(4); *Quinto*, *supra* at 362.

⁶ *Mackey v Dep't of Corrections*, 205 Mich App 330, 333; 517 NW2d 303 (1994).

⁷ *Pauley v Hall*, 124 Mich App 255, 263; 335 NW2d 197 (1983).

allegation by some independent evidence.”⁸ Moreover, while it is generally considered premature to grant a motion for summary disposition before discovery is completed, it may be proper if further discovery would be unlikely to uncover factual support for the nonmoving party’s position.⁹ Summary disposition is not prematurely granted if the party’s argument fails as a matter of law.¹⁰

Several statutory provisions govern the circumstances under which manufacturers and sellers may be held liable in product liability suits. We address four of these below, and explain why Michal’s failure to provide evidence to meet these statutory requirements justified the trial court’s grant of summary disposition of her claims.

C. Rebuttable Presumption Of Nonliability

First, Michal failed to rebut the presumption of manufacturer nonliability in MCL 600.2946(4), which provides in part:

In a product liability action brought against a manufacturer or seller for harm allegedly caused by a product, there is a rebuttable presumption that the manufacturer or seller is not liable if, at the time the specific unit of the product was sold or delivered to the initial purchaser or user, *the aspect of the product that allegedly caused the harm* was in compliance with standards relevant to the event causing the death or injury set forth in a federal or state statute or was approved by, or was in compliance with regulations or standards relevant to the event causing the death or injury promulgated by, a federal or state agency responsible for reviewing the safety of the product.¹¹

Although Michal presented a letter from the FDA to Hammer indicating that there may have been an inadequate amount of *guaifenesin* in Maximum Strength Ephedrin, Michal presented no evidence that the dosage of *ephedrine*, which was the aspect of the product that allegedly caused the harm, was not in compliance with federal regulations. Further, Michal presented no admissible evidence to support her claim that defendants fraudulently misrepresented their products as stimulants, or that defendants fraudulently failed to reveal studies relating to their products’ dangers. In light of the fact that Michal had over a year between the filing of the suit and the summary disposition hearing in which to develop this evidence, it is unlikely that further discovery would uncover factual support for her position. Therefore, the trial court’s granting of summary disposition was justified, and was not premature.¹²

⁸ *Bellows v Delaware McDonald’s Corp*, 206 Mich App 555, 561; 522 NW2d 707 (1994).

⁹ *Village of Dimondale v Grable*, 240 Mich App 553, 566; 618 NW2d 23 (2000).

¹⁰ *Sclafani v Domestic Violence Escape*, 255 Mich App 260, 263 n 2; 660 NW2d 97 (2003), citing *Mackey*, *supra* at 334.

¹¹ MCL 600.2946(4) (emphasis added).

¹² *Village of Dimondale*, *supra* at 566.

D. Existence Of Alternative Production Practice

Second, Michal's claims that defendants' products were defective were properly dismissed under MCL 600.2946(2), which requires a plaintiff alleging a production defect to prove that "a practical and technically feasible alternative production practice was available that would have prevented the harm without significantly impairing the usefulness or desirability of the product to users and without creating equal or greater risk of harm to others." Michal offered no evidence of an alternative production practice that would have avoided the danger of ephedrine misuse while still providing an effective treatment for the symptoms of asthma.

E. Harm Caused By Inherent Characteristic Of The Product

A related concept appears in MCL 600.2947(5), which provides:

A manufacturer or seller is not liable in a product liability action if the alleged harm was caused by an inherent characteristic of the product that cannot be eliminated without substantially compromising the product's usefulness or desirability, and that is recognized by a person with the ordinary knowledge common to the community.

In this case, the harm was caused by the active ingredient ephedrine. Having reviewed the record, we have no reason to believe, and Michal does not argue, that ephedrine could have been eliminated from defendants' products without substantially compromising the products' effectiveness for the legitimate purpose of treating asthma. This provision provides further justification for summary disposition.

F. Failure To Warn

Finally, Michal's failure-to-warn claims were properly dismissed under MCL 600.2948(2), which provides that "[a] defendant is not liable for failure to warn of a material risk that is or should be obvious to a reasonably prudent product user or a material risk that is or should be a matter of common knowledge to persons in the same or similar position as the person upon whose injury or death the claim is based in a product liability action." While it is true that the labels did not specifically warn that death was a possible side-effect of an overdose, in our view, it is a matter of common knowledge that taking an overdose of over-the-counter drug may cause serious medical consequences up to and including death, particularly where, as here, the label indicates the drug is only intended for those who have been diagnosed by a doctor with a specific disease. Accordingly, because the risk of serious harm should have been obvious, the failure-to-warn claims were properly dismissed.

In view of our disposition, we need not reach the remaining arguments.

Affirmed.

/s/ William C. Whitbeck
/s/ Pat M. Donofrio